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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/616,390	07/09/2003	Harold N. Trick	KSURF-08151	9787

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EXAMINER	
IBRAHIM, MEDINA AHMED	
ART UNIT	**PAPER NUMBER**
1638	
MAIL DATE	**DELIVERY MODE**
09/18/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/616,390	TRICK ET AL.	
	Examiner	Art Unit	
	Medina A. Ibrahim	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 July 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,7-9,14-23,26-38,40 and 41* is/are pending in the application.

4a) Of the above claim(s) *7,8,14,21,22,37 and 41* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,9,15-20,23,26-36,38,40 and 42* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 07/10/07 has been entered.

Claims 1, 7-9, 14-23, 26-38, and 40-41 are pending.

Claims 7-8, 14, 21-22, 37, and 41, are drawn to an invention nonelected with traverse in the response of 03/27/06. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144). See MPEP § 821.01.

Claims 1, 9, 15-20, 23, 26-36, 38, 40, and 42 are under examination. Claims 1, 15, 23, 26, and 42 are amended.

Claim Objections

Claims 27 and 28 are objected for failing to further limit parent claim 26. The claims recite plant parasitic nematodes and animal parasitic nematodes, respectively, which are broader in scope than soybean cyst nematodes or Heterodera glycines. It is suggested that claims be cancelled.

Claim Rejections - 35 USC § 112

Claim 23 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 23 is indefinite because "the nucleic acid sequence of claim 15" lacks antecedent basis. Claim 15 is directed to a vector rather than nucleic acid sequence. In the response filed 07/10/07, Applicant has neither amended the claims nor has persuasively argued against the rejection. Therefore, the rejection is maintained.

Claim 28, depending from claim 26 is confusing. Claim 26 is drawn to a method of controlling soybean cyst nematodes, and it is unclear how soybean cyst nematodes can also be animal parasitic nematodes. Clarification is required to more clearly define the metes and bounds of the claim.

Specification

The disclosure is objected to because of the following informalities: for example, page 34, lines 7 and 26; page 52, line 30; page 53, line 25; page 56, line 8, of the specification contains an embedded hyperlink directed to an Internet address. This objection is repeated for the reasons of record as set forth in the last Office action of 06/21/06. In the response of 12/26/06, the specification has been amended, however, the amendment does not obviate the objection because the hyperlink (http) is included in the body of the specification. It is suggested that hyperlink (http) be deleted.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 9, 14-20, 23, 26-36, 38, 40, and 42 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection is repeated for the reasons of record as set forth in the last Office action of 04/06/07. Applicant's arguments filed 07/10/07 have been fully considered but are not deemed persuasive.

The claims are drawn to a transgenic plant comprising a transgenic plant comprising a nucleic acid sequence encoding an orally active double stranded RNA (dsRNA) targeting for genetic inhibition of *Heterodera glycines* embryonic gene, wherein nematodes ingesting said dsRNA nematode RNA do not proliferate; seed of said plant; said dsRNA is complementary to a nematode sterile phenotype gene, a vector comprising said nucleic acid comprising a sense sequence linked to its complementary antisense sequence, operably linked to a promoters; transgenic soybean comprising said vector; a method for controlling soybean cyst nematodes comprising providing said transgenic plant expressing said double stranded RNA, wherein the proliferation of nematodes feeding on said plant is reduced as compared to nematodes feeding on non-

transgenic plant tissue. The claims are also drawn to said method, wherein said nematodes are plant or animal parasitic nematodes, and wherein said double stranded is complementary to a embryonic lethal phenotype gene. The claims are further drawn to said method/vector/transgenic plant, wherein the promoter is tissue specific or constitutive. In contrast, Applicant describes *H. glycines* sequences for major sperm proteins, chitin synthases, and RNA polymerase II sequences. These are genus claims.

The nucleic acids of the claims are described by function only. Applicant has not described the composition and structure of H. glycine embryonic lethal phenotype genes. Prior art searches do not indicate that the genes are well known as of the filing date of Applicant's application. The specification fails to describe a representative number of conserved genes having lethal RNAi phenotypes in *H.glycines*. Unlike the free-living nematode *Caenorhabditis elegans*, the *H.glycines* genome is not fully sequenced and is not well characterized with a number of lethal genes identified through experimental methods. The specification only describes sequences for H.glycines for msp, RNA polymerase II and chitin synthase RNA. Therefore, neither the instant specification nor the prior art describes a representative number of genes essential for H.glycines survival for the production of soybean cyst nematode resistant plants as claimed in the instant application.

The state of the prior art as evidenced by Hussey et al (Braz. J. Plant Physiol., 14(3): 183-194 (2002) is that a large number of plant nematode parasitism candidate genes encoding novel proteins are identified; however, over 70% of the parasitism genes have no homology with functionally annotated genes in the databases. Hussey et

al suggest that the characterization of the target plant parasitism genes is essential before one desires to develop nematode resistant transgenic plants including expression of dsRNA that specifically inhibit target nematode parasitism genes.

Therefore, the claimed invention does not meet the current written description requirements. See, also, the Written description Examination Guidelines published in Federal Registry/Vol. 66, No.4/Friday, January 5, 2001/Notices).

In the response filed 07/10/07, Applicant asserts that the claims have been amended to specify that the dsRNA is orally active and targets for genetic inhibition a *Heterodera glycines* embryonic lethal phenotype gene. Applicant argues that the specification provides specific examples of Heterodera *glycines* that fall within the scope of the claims. Applicant also refers to Table 1 of the specification and to Examples 1-3 to support his position (response, pp. 6-7).

These are not found persuasive because the arguments are not commensurate with the scope of the claims. The amendment to the claims to recite that the dsRNA is orally active and for inhibition of a *Heterodera glycines* embryonic lethal phenotype gene, and the methods of isolating the target gene as in Examples 1-3, would not provide the written description of the dsRNA or the target gene. Genes that are essential for the survival H. glycines including embryonic lethal phenotype genes are not well characterized, and as Hussey et al above suggested the characterization of the target plant parasitism genes is essential before one desires to develop nematode resistant transgenic plants including expression of dsRNA that specifically inhibit target nematode parasitism genes.

In *Eli Lilly and Co.* 43 USPQ2d 1398 (Fed. Cir. 1997), the court stated:

An adequate written description of a DNA "requires a precise definition, such as by structure, formula, chemical name, or physical properties", ... Accordingly, "an adequate written description of a DNA requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it; what is required is a description of the DNA itself (43 USPQ2d at 1404). See also, the MPEP 2163 which states "One must define a compound by "whatever characteristics sufficiently distinguish it". See also in re Koller, 613 F.2d 819, 204 USPQ 702 (CCPA 1980) which requires that "original claims constitute their own description".

The court also stated:

"In claims to genetic material...a generic statement such as 'vertebrate insulin cDNA' or 'mammalian insulin cDNA', without more, is not an adequate written description of the genus because it does not distinguish the claimed genus from others, except by function. It does not specifically define any of the genes that fall within its definition. It doesn't define any structural features commonly possessed by members of the genus that distinguish them from others. One skilled in the art therefore cannot, as one can do with a fully described genus, visualize or recognize the identity of the members of the genus. A definition by function...does not suffice to define the genus because it is only an indication of what the gene does, rather than what it is (43 USPQ2d at 1406).

In response to Applicant's arguments regarding Table, it is noted that the rejected claims do not recite the sequences or subsequences from Table 1 that were shown or were known to have lethal RNAi phenotypes in *H.glycines*. The disclosed embryonic lethal phenotype sequences are not representative of the genus of such sequences for the reasons discussed above.

Applicant alleges that the Examiner has failed to address Applicants arguments regarding the applicability of *Eli Lilly* and the Federal Circuit's recent holding in *Falkner v. Inglis,* 448 F.3d 1357; 79 U.S.P.Q.2D (BNA) 1001 (Fed. Cir. 2006). It is, however, noted that the situation in the instant is not analogous to that in Falkner. The claims in Falkner are limited to poxvirus vectors and poxvirus-based vaccines that were described in details and with five working examples in its patent specification. The claims in the instant application require the use of dsRNA for inhibition of a *Heterodera glycines* embryonic lethal phenotype gene. Neither the instant specification nor the prior art provides a representative number of H.glycine "essential genes" that are known or have been shown to have embryonic lethal RNAi phenotypes in *H.glycines,* much less of their ability to form dsRNA that is orally active upon expression in a transgenic plant. As stated above, the *H.glycines* genome is not well characterized with a number of lethal genes identified through experimental methods. Therefore, a representative number of *Heterodera glycines* genes having lethal RNAi phenotypes are neither described in the instant specification nor were known in the prior art.

An amendment to the claims to the recite specific embryonic lethal phenotype genes sequences or subsequences would obviate the above rejection.

Remarks

The art rejections have been withdrawn in view of Applicant's amendment to the claims and Applicant's arguments.

No claim is allowed.

Contact Information

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Medina A. Ibrahim whose telephone number is (571) 272-0797. The Examiner can normally be reached Monday -Thursday from 8:00AM to 5:30PM and every other Friday from 9:00AM to 5:00 PM. Before and after final responses should be directed to fax nos. (703) 872-9306 and (703) 872-9307, respectively.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Anne Marie Grunberg, can be reached at (571) 272-0795.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

9/16/07
Mai

MEDINA A. IBRAHIM
PRIMARY EXAMINER